Exhibit 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	CIVIL NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HON. ROBERT B. KUGLER

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

VOLUME I

- - -

April 29, 2021

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Videotaped remote deposition of BANDARU VENKATA RAMARAO, taken pursuant to notice, was held via Zoom Videoconference, beginning at 6:08 p.m., India Standard Time, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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any process of API here. So directly API, we are going to take for finished tablets.

Q. Got it. So this is referring to the fact that the finished dose manufacturing process --

A. Exactly, exactly.

Q. -- doesn't create a risk of NDMA. The NDMA was part of the API manufacturing process --

A. Exactly.

Q. -- before it ever got to you?

A. Yes. Exactly.

Q. Got it.

MR. SLATER: Going now down to the bottom half of the page, please.

BY MR. SLATER:

Q. There's a risk evaluation section. It looks like this is now the analysis per the FMEA risk tool, correct?

A. Yes, yes.

Q. And there is -- rephrase.

The first line of the severity of effect table has an effect that's very high. And it says, "The valsartan drug contained NDMA impurity above 0.5 parts per million, caused serious health hazard, rating of five," correct?

A. Yes.

Q. And we're going to come to it, but that was the severity rating, correct?

A. This was given by FDA, of this limit of .5 ppm.

Q. It was given by who?

A. FDA. FDA agency.

Q. By the FDA?

A. Yes.

Q. Okay. So -- rephrase.

Did Hetero perform this analysis, or you're saying this is per the FDA saying that the risk level was very high, the severity is very high?

A. See, by that time, when this has been identified, we do not have any

specified limit for the NDMA presence.

So since there is a presence of NDMA and levels in the API manufacturing, then we got that communication, at that time we don't have any methods to even establish what are the levels which are there.

So immediately, the FDA wanted us to go to the recall. And we initiated the recall. Based on the recall communication given to FDA agency agent, FDA has been given the communication saying that three drug product of -- three finished doses, three batches with higher dose, and you test it and keep as defined .5 ppm limit.

If values are above that, you go for the recall, like there is a communication from FDA.

Basing it on that, we have tested all the three finished product lots are above .5 ppm. That is the result, and then have communicated to agency that there are the levels above .5

ppm.

They recommended us go for the -- for the recall.

Q. So if I boil that down, based on the information that Hetero had, you determined that the severity was at the highest level because of the level of NDMA and because it's a probable carcinogen, correct?

A. Yes.

Q. And that's a few other boxes, which also the rating for occurrence, and the rating for detection and the risk acceptability, et cetera. And we're going to get into the FMEA table later, but that's where these ranking hierarchies come from, correct?

A. Ranking yes.

MR. SLATER: Let's go now if we could, Cheryll, to Page 9 of 12, please.

BY MR. SLATER:

Q. This is the top half, talks about what the API manufacturer was doing

to try to control the NDMA impurity, and they were trying to modify the process so that the sodium nitrite quenching wouldn't react with the DMA from the DMF, correct?

A. Yes.

Q. If you go to the bottom half of the page under risk reduction, it says in the first bullet point that Unit 5 has initiated a recall of all the batches which are within valid shelf life from the market, correct?

A. Yes.

Q. And if I understand correctly, that was based on the fact that since this was a manufacturing process impurity with the API, the understanding was that all of the API would have had the NDMA contamination, so that would have been present in all of the finished dose product, correct?

A. Yes, yes, yes.

MR. SLATER: Let's go if we could, Cheryll, to the Bates

number -- it's one of the annexures. 264 is the last three digits. Perfect.

BY MR. SLATER:

Q. Here on this page, which has the Bates Number 264 as the last 3 digits, this is the FMEA table which we were talking about earlier, correct?

A. Yes.

Q. And we'll walk through it right now.

The first column has the item or function. That's the input which is NDMA impurity identified in valsartan, correct?

A. Yes.

Q. The potential failure mode, this is what can go wrong, is generation of impurity, during drug substance manufacturing process, generation of impurity during drug product manufacturing, unavailability of specification for testing of impurity, unavailability of suitable method for

identification of impurity.

So this is telling us the impurity was created during the manufacturing process, and you don't have any information from the API manufacturer as to a specification, so there's no way for you to test for it.

Do I understand that correctly?

A. Yes.

Q. Then the failure mode effects is what can happen as a result of this. And it says, "Health hazard: Identified impurity is carcinogenic in nature."

So it's saying that this is something that can cause cancer, correct?

A. Yes.

Q. The potential failure clauses, it says, "Impurity not identified during product development," and that's what we've talked about at length here, that the risk assessment did not identify the potential chemical

reactions that led to the NDMA, correct?

A. Yeah.

Q. Then it says, "Current controls. No controls are existing to control the identified impurity in the drug product."

That's meaning at this point it's not being sold with any controls. We haven't gotten to that point, and I think we talked about it a few pages earlier, Unit 1 was trying to come up with a way to get rid of the NDMA as a contaminant, correct?

A. Yes.

Q. Then the risk analysis and evaluation we had started to talk about, the severity was rated a five which is the highest level which is defined as very high with a serious health hazard, correct?

A. Yes.

Q. And then the PF, if I understand correctly, that would be the probability of it occurring and I looked

at that from the occurrence rating table as very high because it's a five meaning failure is almost inevitable, correct?

A. Yes.

Q. And then I looked at the detection rating table which we had just looked at a few moments ago, Level 5, detection none. There are no detection controls existing or cannot detect any failure occurring.

And that's because, again, you don't have a specification from the API manufacturer to even look for it, correct?

A. Correct.

Q. Then the RPN, which I understand to be the risk priority number, is calculated by multiplying the severity times the probability times the detection, and five times five times five is a maximum risk priority number of 125, correct?

A. Correct.

Q. And 125, as I looked through

the FMEA protocols means it's intolerable, intolerable, the highest possible score, correct?

A. Yes.

MR. SLATER: Cheryll, can you turn to the last three digits are 290, please.

BY MR. SLATER:

Q. My understanding is what we're looking at on this page and in more particularly the bottom half of the page is the testing procedure for NDMA that was being established by Unit 1; is that correct?

A. Yes.

Q. So they provided this information to you so you could then provide this document with this information to the FDA, correct?

A. Correct.

Q. And I don't think I stated that earlier, but this document was provided to the FDA, correct?

A. Yes.